UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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JUL 7 1992

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SUBJECT: Dietary Exposure Analysis for the Proposed Use of Pinnacle® (Thifensulfuron Methyl) on Field Corn (PP0F3872)

FROM: Stephen A. Schaible
Dietary Exposure Section
Science Analysis Branch/HED (H7509C)

TO: R. J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (H7505C)

THROUGH: James P. Kariya, Head
Dietary Exposure Section
Health Effects Division

Action Requested

Provide a dietary exposure analysis for the proposed use of thifensulfuron methyl on field corn. The active ingredient is also known as DPX-M6316 and is the active ingredient in Harmony® Herbicide.

Discussion

1. Toxicological Endpoint: The Dietary Risk Evaluation System (DRES) routine chronic analysis used a Reference Dose (RfD) of 0.013 mg/kg body weight/day, based on a no observed effect level (NOEL) of 1.25 mg/kg bwt/day and an uncertainty factor of 100. The NOEL is taken from a two year feeding study in rats which demonstrated as an effect lower body weight gains in males. Serum sodium in males and females was sporadically lower throughout the study. This RfD has been approved by both the HED (2/25/88) and Agency (3/23/88) RfD committees.

2. Residue Information: Food uses evaluated in this analysis were the published tolerances (for barley, soybeans, and wheat) listed in 40 CFR 180.439 and the proposed use on field corn at 0.05 ppm. Detectable secondary residues in meat and milk (incl. poultry and eggs) are not expected from these uses (personal communication, R. Cook, 7/7/92). The DRES representations of field corn are "corn, grain-endosperm", "corn, grain-bran", "corn sugar", and "corn, grain-oil".

A summary of the residue information used in this analysis is attached as Table 1.

3. Exposure Analysis: The DRES chronic exposure analysis used tolerance level residues and one hundred percent crop treated to estimate the Theoretical Maximum Residue Contribution (TMRC) for the overall U.S. population and 22 population subgroups. A summary of the TMRCs and their representations as percentages of the RfD for the general population and the 22 subgroups is attached as Table 2.

The TMRC for the overall population from published uses is 0.000108 mg/kg bwt/day, which represents 0.8% of the RfD. The proposed use on field corn would contribute 0.000017 mg/kg bwt/day (0.13% of the RfD) and would raise the TMRC to 0.000125 mg/kg bwt/day, or close to 1% of the RfD. The subgroup most highly exposed, children aged one through six, has a TMRC from published and proposed uses of 0.000266 mg/kg bwt/day (2% of the RfD), with the proposed use contributing 0.000044 mg/kg bwt/day (0.3% of the RfD) to the TMRC.

The exposure values calculated in this analysis are probably overestimates, given that tolerance level residues and 100 percent crop treated were assumed. Even so, the chronic risk posed through the diet by this chemical appears to be minimal.

Attachments

cc: DES, CBTS, Tox 2, A. Kocialski, Caswell # 573S

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 573S DATE: 07/01/92 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Harmony (DPX-M6316) Caswell #573S CAS No. 79277-27-3 A.I. CODE: 128845 CFR No. 180.439	2yr feeding- rat NOEL= 1.2500 mg/kg 25.00 ppm LEL= 25.0000 mg/kg 500.00 ppm ONCO: Negative- 2 species.	Lower body wt gains in M, serum sodium in M & F were sporadically lower thoughout the study. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000	No data gaps.	HED complete 02/25/88. EPA verified 03/23/88. On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
15029AA	SOYBEANS-SPROUTED SEEDS	8F3663			0.100000
24001AA	BARLEY	6F3431			0.050000
24002EA	CORN,GRAIN-ENDOSPERM	0F3872	0.050000		
24002HA	CORN,GRAIN-BRAN	0F3872	0.050000		
24002SA	CORN SUGAR	0F3872	0.050000		
24007AA	WHEAT-ROUGH	6F3431			0.050000
24007GA	WHEAT-GERM	6F3431			0.050000
24007HA	WHEAT-BRAN	6F3431			0.050000
24007WA	WHEAT-FLOUR	6F3431			0.050000
27002OA	CORN,GRAIN-OIL	0F3872	0.050000		
27010OA	SOYBEANS-OIL	8F3663			0.100000
28023AA	SOYBEANS-UNSPECIFIED	8F3663			0.100000
28023AB	SOYBEANS-MATURE,SEEDS DRY	8F3663			0.100000
28023WA	SOYBEANS-FLOUR, FULL FAT	8F3663			0.100000
28023WB	SOYBEANS-FLOUR, LOW FAT	8F3663			0.100000
28023WC	SOYBEANS-FLOUR,DEFATTED	8F3663			0.100000

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TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 07/01/92 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Harmony (DPX-M6316) Caswell #573S CAS No. 79277-27-3 A.I. CODE: 128845 CFR No. 180.439	2yr feeding- rat NOEL= 1.2500 mg/kg 25.00 ppm LEL= 25.0000 mg/kg 500.00 ppm DNCD: Negative- 2 species.	Lower body wt gains in M, serum sodium in M & F were sporadically lower thoughout the study. No evidence of oncogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.013000 EPA RfD= 0.013000	No data gaps.	HED complete 02/25/88. EPA verified 03/23/88. On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000107	0.000124	0.954569	0.128438		
U.S. POPULATION - SPRING SEASON	0.000104	0.000121	0.928000	0.124931		
U.S. POPULATION - SUMMER SEASON	0.000106	0.000123	0.942762	0.131208		
U.S. POPULATION - FALL SEASON	0.000111	0.000128	0.982131	0.131131		
U.S. POPULATION - WINTER SEASON	0.000109	0.000126	0.965446	0.126515		
NORTHEAST REGION	0.000108	0.000120	0.924623	0.091262		
NORTH CENTRAL REGION	0.000110	0.000125	0.964708	0.116100		
SOUTHERN REGION	0.000103	0.000124	0.951169	0.155838		
WESTERN REGION	0.000109	0.000128	0.986131	0.149200		
HISPANICS	0.000106	0.000135	1.040877	0.228862		
NON-HISPANIC WHITES	0.000109	0.000124	0.955277	0.113592		
NON-HISPANIC BLACKS	0.000096	0.000119	0.914754	0.178377		
NON-HISPANIC OTHERS	0.000103	0.000118	0.905831	0.114946		
NURSING INFANTS (< 1 YEAR OLD)	0.000064	0.000080	0.611900	0.122031		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000222	0.000271	2.080815	0.375815		
FEMALES (13+ YEARS, PREGNANT)	0.000074	0.000086	0.661254	0.089946		
FEMALES 13+ YEARS, NURSING	0.000095	0.000106	0.813246	0.080662		
CHILDREN (1-6 YEARS OLD)	0.000222	0.000265	2.040038	0.333015		
CHILDREN (7-12 YEARS OLD)	0.000165	0.000196	1.507292	0.240792		
MALES (13-19 YEARS OLD)	0.000120	0.000139	1.066785	0.147238		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000093	0.000109	0.835638	0.119885		
MALES (20 YEARS AND OLDER)	0.000090	0.000101	0.776162	0.080492		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000072	0.000081	0.624015	0.070192		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

TOLERANCE ASSESSMENT SUMMARY FOR Harmony (DPX-M6316) DATE: 07/01/92
CASWELL #573S

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000108	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	0.826	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000017	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.128	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000125	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	0.955	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000222	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	1.705	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000049	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.376	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000271	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	2.081	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

ANALYSIS FOR POPULATION SUB-GROUP: CHILDREN (1-6 YEARS OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000222	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	1.707	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000044	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	0.333	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.000266	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	2.040	% OF THE ADI.

NO OTHER PENDING TOLERANCES ARE IN THE FILE

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Chemical:	**Thifensulfuron methyl**
PC Code:	**128845**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**07/07/92**
File ID:	**00000000**
Accession Number:	**412-03-0019**

HED Records Reference Center
01/09/2003